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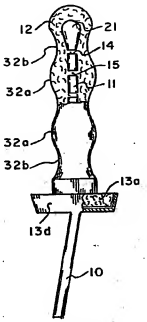
(54) Title: POLYMERIC DRUG DELIVERY APPLICATORS

(57) Abstract

Topical applicators of a porous cellular nature (12) which are primarily designed to be used on the mucous membranes of human or animal body cavities such as the vaginal tract. The invention has particular application to low cost, mass volume, disposable devices pre-impregnated with dry, liquid or semi-liquid therapeutic compositions (102).



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AMENDED CLAIMS
(received by the International Bureau on 11 February 1981 (11.02.81))

1. An applicator for treating a body cavity comprising:
a centrally located core member;
a polymeric foam element of predetermined shape substantially surrounding and being secured to said core member;
said foam element containing between 10 and 60 percent by weight of the foam an additive selected from a group consisting of medicaments, bactericides, antibiotics, germicides, fungicides, spermicides, soaps, detergents and emollients dispersed uniformly therein.

2. An applicator as claimed in Claim 1 wherein said foam element has a densely structured cellular matrix of between approximately 6 to 30 lbs./ft.^{3} and is comprised of normal and abnormal cells, said abnormal cells including ruptured, collapsed, distorted and swollen cells and further including fibrous threads of polymeric material interwoven throughout the cellular matrix thereof.

3. The applicator of Claim 1 wherein said polymeric foam element includes a smooth pliable porous skin surface.

4. The applicator of Claim 1 further including a soluble covering on at least part of the surface of said polymeric foam element.

5. The applicator of Claim 4 wherein said covering is removable from said polymeric foam element.

6. The applicator of Claim 4 wherein said soluble covering includes a medicament therein.

7. The applicator of Claim 4 wherein said soluble covering is comprised of a plurality of layers at least one of which includes a medicament therein and wherein

said plurality of layers are soluble at different rates of time.

8. The applicator of Claim 1 wherein at least part of said additive includes effervescent means.

9. The applicator of Claim 1 wherein at least part of said additive is encapsulated.

10. The applicator of Claim 1 wherein at least part of said additive includes means for time releasing the same.

11. The applicator of Claim 1 including a handle portion extending outwardly from said polymeric foam element and being securely connected to said core member.

12. The applicator of Claim 11 wherein said handle portion is substantially flexible.

13. The applicator of Claim 1 further including an enlarged element adjacent the base of said polymeric foam element and extending transversely thereof.

14. The applicator of Claim 13 wherein said enlarged element is substantially leak proof.

15. The applicator of Claim 1 wherein said core member is substantially hollow and further including a rod-shaped plunger element adapted to be slid into and out of said hollow core member.

16. The applicator of Claim 1 wherein said core member is substantially hollow and further including a plurality of holes passing through the walls of said hollow core member thereby allowing communication between the interior of said hollow core member and said polymeric foam element.

17. The applicator of Claim 16 wherein said core member includes a base adapted to be secured to the open end of a container with said polymeric foam element being located either in said container or extending outwardly away from said container.

18. The applicator of Claim 1 wherein said polymeric foam element is highly hydrophilic, being capable of absorbing up to 25 times its own dry weight of water.

19. A method of producing an applicator for treating a body cavity comprising the steps of:

mixing a polymeric foamable material to obtain a partial polymerized mass;

adding a predetermined additive to said mass, said additive being selected from the group consisting of medicaments, bactericides, antibiotics, germicides, fungicides, spermicides, soaps, detergents and emollients;

mixing said combined mass and additive to substantially evenly disperse said additive;

pouring the mixture into a mold and forming the same into a predetermined shape.

20. The method of Claim 19 including the step of positioning a support structure in said mold to be joined with said polymeric material.

21. The method of Claim 19 further including the step of minimizing foaming during said second mixing step.

22. The method of Claim 19 including the step of encapsulating said additive prior to adding the same to said mass.

23. The method of Claim 19 including the step of coating the outer surface of the polymeric material formed in said mold with a soluble coating material.

24. The method of Claim 23 wherein said coating step includes the step of lining the mold walls with said coating material.

25. The method of Claim 23 wherein said coating step includes the step of preforming a soluble sheath and sliding said sheath over said outer surface.

26. The method of Claim 19 wherein said first mixing step includes mixing a prepolymer urethane resin with a catalyst at 500 to 2500 RPM for 30 to 100 seconds.

27. The method of Claim 19 wherein said second mixing step includes mixing said combined mass and additive at 250 to 1000 RPM for 15 to 100 seconds.

EDITORIAL NOTE

The applicant failed to renumber the amended claims in accordance with Section 205 of the Administrative Instructions.

Original claims 1 to 97 have been cancelled and, accordingly amended claims 1 to 27 are new.